DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington DC 20204

OCT 19 1999 1436 '99 OCT 22 P1:30

Michael J. Ellis
Chief Executive Officer
Metabolife International, Incorporated
5070 Santa Fe
San Diego, California 92109

Dear Mr. Ellis:

This is in response to your letter to the Commissioner of Food and Drugs, Dr. Jane E. Henney, M.D., dated August 11, 1999, requesting that the Food and Drug Administration (FDA or the agency) establish a new working group to design a better system for adverse events reporting and to promulgate guidelines for dietary supplements containing ephedrine alkaloids and other herbal dietary supplements. The agency appreciates the willingness of dietary supplement maunfacturers to work with the agency on all matters surrounding the regulation of dietary supplements. The agency has already initiated several activities in this regard.

As you may be aware, the Commission on Dietary Supplement Labels released its final report on November 24, 1997. In its report, the Commission, among other things, urged the FDA, industry, the scientific community, and consumer groups to work together voluntarily to improve passive postmarketing surveillance systems. FDA responded to this guidance by establishing a Working Group of FDA's Foods Advisory Committee to consider the issue of postmarket surveillance. The working group, which is just beginning its review, is composed of individuals representing the dietary supplement industry, the scientific community, FDA, and consumers. The working group is charged with suggesting and evaluating approaches for improving postmarket passive surveillance and for improving communication of real and potential product safety issues.

Additionally, FDA has held two public meetings -- on June 8, 1999 in Washington, D.C. and on July 20, 1999 in Oakland, California -- at which the agency solicited comments on the development of an overall strategy for achieving effective regulation of dietary supplements under the Federal Food, Drug, and Cosmetic Act (the act) as amended by the Dietary Supplement Health and Education Act. In the Federal Register notices announcing these meetings, the agency specifically requested comments on the adverse event monitoring system (64 FR 32880 (June 18, 1999) and 64 FR25889 (May 13, 1999)). Presently, the agency is reviewing the comments and information it has received in response to its request for public comments on the development of the strategy. We have forwarded your letter to Dockets Management Branch to be included in the docket created for comments related to

99N-1174

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the regulation of dietary supplements (docket No. 99N-1174), including dietary supplement adverse event reporting. We will consider the information in your letter, along with all other comments, as we move forward on this matter.

While we are considering how to improve the adverse event reporting system, we agree with you that greater cooperation among FDA, industry, and other interested parties to enhance the effectiveness of the current system would improve the ability of this system to identify potential safety problems and thereby improve their public health utility. In this regard, we encourage Metabolife International and other interested parties to submit reports of adverse events associated with the use of dietary supplements and other scientific and medical data that you have to FDA. Reports of adverse events may be submitted to Adverse Event Monitor, Food and Drug Administration, 200 C Street, S.W. (HFS-452), Washington, D.C. 20204.

Please contact us, if we may be of further assistance.

Sincerely yours,

Joseph A. Levitt
Director
Center for Food Safety
and Applied Nutrition

cc:
HFA-224, w/incoming
HFA-305, docket 99N-1174
GCF-1, Dorsey
HFS-1, r/f
HFS-3, Oliver
HFS-22, Gordon, CCO
HFS-450, Yetley
HFS-456, Carlson

R/D:HFS-456:MCarlson:9/2/99
Revised:HFS-456:RMoore:9/7/99
Revised:HFS-450:EYetley:9/10/99
Revised:HFS-450:9/15/99
Revised:HFS-22:PSalsbury:9/15/99
F/T:dyh:10/13/99

Metabolife International, Inc.™

August 11, 1999

Jane E. Henney, M.D.
Commissioner of Food and Drugs
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857
via fax: 301.443.3100

Dear Dr. Henney:

Since the passage of the Dietary Supplement Health and Education Act in 1994, the FDA has been operating under a Congressional mandate to establish a new regulatory environment for dietary supplements. Over the same period of time, the herbal supplement market has expanded exponentially.

The agency and the industry are facing a formidable challenge: develop entirely new programs that will instill consumer confidence in the quality and safety of this special class of products -- and do it quickly.

I believe that FDA and the herbal industry can best achieve their goals by working together. The fruits of an adversarial relationship, which admittedly we have had in the past, resulted in a flawed process that has failed to yield effective guidelines based on sound science.

If the report released last week by the General Accounting Office tells us one thing, it is that meaningful and effective federal guidelines are impossible if they are based on an unreliable adverse event reporting system. Metabolife believes that responsible herbal companies can only succeed in meeting consumers' needs with the help of meaningful and effective guidelines promulgated by the FDA.

We don't have a good reporting system. This industry is getting bigger and bigger. The only responsible thing is to have some kind of program that works. I believe that the responsible companies in the industry are prepared to come forward and work with the FDA to develop a program. The only way to better serve the consumer is for industry and the FDA to work together.

I propose that the FDA set up a new working group composed of scientists, agency experts, consumers, herbalists and industry to design a better system for reporting suspected adverse health events and promulgate federal guidelines for dietary supplements containing herbal ephedra. A successful effort by this working group would provide a template for establishing federal guidelines for all herbal products.

99N-1174 C60 99-50

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Industry can provide valuable scientific and medical data on the formulation and biochemistry of herbs, as well as volumes of data on consumption experience. Half of all Americans, at least, are using herbal supplements. Some media are talking about health events based on medically and scientifically unreliable reports. This is causing public confusion that is not serving the consumer. We need standards that instill consumer confidence and help people make fully informed decisions about the responsible use of herbs.

Metabolife International, as the maker of American's best selling herbal supplement for weight loss, will fully support all efforts to develop a new monitoring program and to promulgate federal guidelines based on sound scientific and medical data.

Please feel free to contact me personally if Metabolife can in any way be of service in launching a new initiative to establish standards for herbal products.

Sincerely,

Michael J. Ellis, CEO
Metabolife International, Inc.

METABOLIFE INTERNATIONAL, INC.
5070 Santa Fe Street
San Diego, CA 92109
(619) 490-5222
Fax: (619) 490-4217

facsimile transmittal

To:	Jane E. Henney, MD	Fax:	(301) 443-3100
Company:	US Food & Drug Administration	Phone:	
From:	Michael J. Ellis	Date:	08/10/99
Re:		Pages:	3
CC:			

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